BACKGROUND

The North Atlantic Region Medical Command (NARMC) supports a very large number of active duty, dependant and retiree patients who may required temporary or indefinite anticoagulation therapy. Currently most military patients taking Coumadin® are followed in a "Coumadin Clinic" which reviews lab tests of clotting times and advises changes to patients' Coumadin® doses as well as time intervals for repeat blood testing. The Walter Reed Army Medical Center (WRAMC) Coumadin Clinic alone has approximately 550 patients enrolled and managed. This is a high-risk, resource-intensive service and may involve serious and costly complications if not done well.

BACKGROUND

The antithrombotic agent Coumadin® is a drug of proven benefit in appropriate patients for reducing complications such as stroke, pulmonary embolism, and fatal malfunction of prosthetic cardiac valves. Such events clearly have significant impact in terms of morbidity or disability for patients, lost productivity, and economic liability for the medical facility. The dose of Coumadin® used by a patient is not fixed and must be adjusted according to the results of a periodic lab test called International Normalized Ratio (INR). In standard practice, this requires multiple trips to the lab for patients and multiple telephone calls by both patients and clinic personnel. Detection of changes in patient condition, interval development of new medical problems, changes to therapy by another provider, missed doses, and complications which may have developed relies heavily on patient self-reporting, is not uniform and may occur only after a delay and multiple contacts. This accepted standard of care generally does not facilitate proactive intervention and may not optimize efficacy of the therapy.

METHODS

A patient self-test (PST) device, International Technynidyne Corporation's (ITC) ProTime® Microcoagulation System, is available to allow in-home determination of INR. A Web-based, programmable home monitoring system, the Health Hero Network's (HHN) HealthBuddy®, has been used successfully in diabetics to date. The HealthBuddy®, which attaches to a patient's telephone line and does not require use of a computer, should be adaptable to allow Coumadin® patients to report changes in condition, problems with therapy, and complications. We expect such a monitoring capability to increase the supervising practitioner's ability to optimize therapy and track, if not avert, complications and failures of the therapy. Further interaction would take place during a much shortened time interval and would more quickly identify high-risk patients, allowing more timely and effective intervention.

The WRAMC Coumadin Project will evaluate approximately 400 patients divided into four different groups for a period of one year. Group 1 is a control group receiving standard lab testing and telephone monitoring. Group 2 will test the use of the ProTime® PST technology in a military population. Group 3 will use the HealthBuddy® to communicate interactively with the WRAMC Coumadin® Clinic via the Web. Group 4 will receive both devices.

OUTCOMES

By investigating the safety and efficacy of both PST and remote interactive monitoring of patients on anticoagulation therapy, the WRAMC Coumadin Clinic may be able to:

1) increase the success of the therapy and therefore limit risk to the patient from their conditions (decrease complications)

2) decrease the risk to patients of the therapy itself

3) decrease hospitalization and associated costs of treatment of patients either failing therapy or suffering complications of therapy

4) limit cost, time, and productivity lost to therapy

5) suggest multiple other conditions which also require a large investment of resources to which this technology may be adaptable

CONCLUSION

Coumadin® therapy is a powerful tool for treating multiple medical conditions that are frequently developed by Active Duty and DoD personnel, as well as, by the general beneficiary population. It has, however, the potential for generating serious complications including mortality and is very time- and labor- intensive to supervise properly. Even uneventful and limited therapy may require lengthy absences from duty/work for the affected patient. Both complications and failures of this therapy can be extremely costly both in human terms and in expense to the military health care system. With patient self- monitoring and modern day technology to assist, we can extend the management of this and other medical conditions occurring in the Active Duty population and to service members stationed at a distance from military medical care throughout all military services. This project is well suited for wide-scale adaptation on the regional level with services provided by a well-equipped medical center.

PROJECT MILESTONES

ACQUISITIONS

- Personnel
  - Project Manager ✓
  - Nurse Practitioner ✓
  - Research Associate ✓
  - Data Management Technician

- Equipment & Supplies
  - Office Equipment ✓
  - Office Supplies ✓
  - Medical Equipment
    - HealthBuddies® [25%]
    - ProTime® Units [4%]
  - Medical Supplies [4%]

PROJECT MILESTONES
(Continued)

ADMINISTRATIVE SUPPORT

- Develop Project Work Breakdown Structure ✓
- Develop New Human Use Research Protocol and Obtain Approvals ✓
- Develop New Patient Consent Form and Obtain Approvals ✓
- Develop and Process No- Cost Agreements ✓
- Develop Specialized Project Forms ✓
- Develop Master Patient Records ✓
- Prepare Copies of Patient Record (420 copies) [25% Complete]
- Develop Patient Tracking System/Database [20% Complete]
- Enter Patient Data into Tracking System/Database [Pending]
- Develop Equipment Issue Process ✓
- Develop Patient Selection Process ✓
- Develop Randomization Process ✓
- Develop Patient Training Program ✓
- Develop Clinical Business Process

PROJECT MILESTONES
(Continued)

CLINICAL STAFF TRAINING

- Clinic Process ✓
- ITC ProTime® Device ✓
- HHN HealthBuddy® Device ✓
- HHN Software Application ✓

PATIENT CARE/SUPPORT

- Qualification ✓
- Selection ✓
- Randomization ✓
- Training (ITC and HHN Devices) [ongoing]
- Enrollment [ongoing]
- Tracking [ongoing]

PROJECT MILESTONES
(Continued)

REPORTING REQUIREMENTS

- WRAMC Telemedicine Directorate
- WRAMC Department of Clinical Investigation
  - 2001 Annual Report ✓
  - 2002 Annual Report
- Telemedicine and Advanced Technology Research Center (TATRC)
  - Midyear Report ✓
  - Final Report ✓
- Medical Research and Materiel Command (MRMC)
- Commander's ATA Review Board [2001 Annual Report] ✓
- International Technidyne Corporation [enrollment reports]
- Health Hero Network [enrollment reports]

FORMS DEVELOPMENT BY GROUP

Patient Project Consent Form (G. 1,2,3,4)

Coumadin® Clinic Consent Form (G. 1,2,3,4)

Patient Coumadin® Information Sheet (G. 1,2,3,4)

Coumadin® Study Registration Form (G. 1,2,3,4)

Recreation of SF-36 Health Survey (G. 1,2,3,4)

Patient Encounter Form (G. 1,2,3,4)

Baseline Patient Satisfaction Survey (G. 1,2,3,4)

Clinic Testing Data Collection Form - Clinical Test Patients (G. 1,3)

FORMS DEVELOPMENT BY GROUP (CONTINUED)

Tri-Monthly Patient Clinic INR Testing Satisfaction Survey (G. 1,3)

Tri-Monthly Patient Clinic Health Monitoring Satisfaction Survey (G. 1,2)

Patient Self Testing Data Collection Form (G. 2,4)

Clinical Data Collection Form – Self Test Patients (G. 2,4)

Patient Self Testing Time Requirement Data Collection Form (G. 2,4)

Laboratory Testing Time Requirement Data Collection Form (G. 1,3)

Tri-Monthly Patient Self Testing Satisfaction Survey (G. 2,4)

Referring Provider Satisfaction Survey A (G. 2,4)

Referring Provider Satisfaction Survey B (G. 3,4)

Tri-Monthly Patient Health Buddy Satisfaction Survey (G. 3,4)

Health Buddy Custom Dialog Questions (G. 2,3,4)

PROBLEMS / CHALLENGES

Infrastructure Needs:
- Acquiring Required Supplies and Equipment
- Office Space for Staff and Patient Care
- Communications (Phone / LAN)
- Personnel
- Parking

Administrative Needs:
- No Existing Operational Patient Record System
- Identify Active Coumadin Clinic Patients
- Making 400 copies of Project Patient Medical Record

Scientific/Clinical Needs:
- Design of Required Project Forms
- Conduct Manual Review of Medical Records
- Creation of Master Patient Record for each of Four Groups
- Set Up of New Individual Patient Medical Record

Technical Needs:
- Creation of a Patient Tracking System/Database

PROBLEMS / CHALLENGES
(Continued)

Protocol and Consent Form Approvals through Local DCI
- Human Use
- Institute Review Board

Logistics:
- Acquiring Required Equipment and Supplies in a Timely Manner
- Patient Scheduling for Initial Half-Day Coumadin® Clinic Briefing
- Patient Scheduling for Enrollment into Coumadin® Project

Training:
- Initial Staff Training on
  - ITC ProTime® Device
  - HHN HealthBuddy® Device
  - HHN Server Application
- Patient Training:
  - ITC ProTime® Device

TRAINING REQUIREMENTS

Staff Training on Project Study Methods

Staff Training on Consent Form and Protection of Human Subjects

Staff Training on ProTime® Device

Staff Training on HealthBuddy® Device

Staff Training on Health Hero Network's Application Software

Staff Training on Blood Handling/Hazards/Safety

Patient Training on Coumadin® Medication and Interactions

Patient Training on Clinic Operation and Methods

Patient Training on ProTime® Device

Patient Training on HealthBuddy® Device

Project Costs To Date

Personnel:		**$181,773**
Principle Investigator (20%):		
Project Manager (30% FTE):		
Nurse Practitioner (100% FTE):		
Research Consultant (10% FTE):		
Data Management Technician (20% FTE):		
Telemedicine Logistics (Percentage):		
Clinic Equipment:		
Storage Cabinet (2):	$423	
File Cabinet:	$211	
Shredder:	$150	
PC (3):	$9,470	
Printer:	$1,344	
Answering Machines (3):	$95	
Refrigerator:	$435	
		$12,128
Travel:		$3,500
Clinic Office Supplies:		$1,834
Expendable Medical Supplies:		$2,606
		$201,841

Project Costs To Date

Virtual Costs:

Home Health Hero Network System	
Site Fee:	**$25,000**
Patient Activation/Health Buddy:	**$20,000**
Monthly Usage Fee:	**$36,000**
	$81,000
ITC ProTime Device Purchase Fee:	**$300,000**
	$381,000